REMARKS

The foregoing amendment cancels all of the claims of the pending application and inserts a new set of claims including apparatus claims 45 – 81 and method claims 82 – 106. The new set of claims is submitted to specifically address the technical objections to the claims and the prior art rejections set forth in the latest Office Action. Reconsideration of the present application in light of the new claims and following remarks is respectfully requested.

At the outset, the Office Action indicates that former claim 39 was allowable over the prior art. New claims 76 and 101 essentially correspond to former claim 39 and are therefore likewise deemed patentable over the prior art. However, for the reasons presented below, Applicants submit that all of the claims in the present application are in allowable condition.

New claim 45 is directed to an apparatus for the treatment of a skin disorder in which the skin disorder lies at or near the surface of the skin of the patent such as acne and seborrhea (see claim 81). The apparatus employs at least one light source comprising spectral emittance means for delivering to the skin disorder of the patient a spectral emittance of light energy in a plurality of discontinuous applications in which each application is delivered at a dose of at least 9 Joules/cm^2 in the at least substantial absence of UV radiation. The spectral emittance is in at least one, preferably narrow, spectral band in which one of the spectral bands is in the spectral

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range of 405 - 440nm. Claim 52 specifically covers an embodiment of the invention wherein the principal spectral emittance for treating the skin disorder is in the range of 405 to 440nm.

The limitation of the dose level to at least 9 Joules/cm^2 is based on the disclosure in the specification at page 6, lines 16-19 wherein illumination intensity (i.e. power density) is stated to be in the range of 10mW/cm^2 – 500mW/cm^2 as well as the disclosure at page 19, lines 13-16 showing an illumination period of from 15 to 60 minutes at a power density of 20mW/cm^2. Taking the minimum power density (10mW/cm^2) times the minimum treatment period (15 minutes, i.e. 900 seconds) provides a dose of 9000mJ/cm^2 or 9 Joules/cm^2. This dose level is the minimum necessary when applied in a plurality of discontinuous treatments to induce the acne bacteria (P. acne) population to produce prophoryins and thereby keep the bacterial colony size below the critical mass which the bacteria requires for continued proliferation.

It should be understood that the accumulated radiation energy dose in Joules/cm^2 provided in a plurality of discontinuous applications is the crucial parameter for the treatment of skin disorders such as acne and seborrhea. It has been shown in in-vitro experiments on acne bacteria colonies, as well as in clinical studies, that the crucial parameter that defines the effective destruction of the acne bacteria by exposure to light, is the total dose radiated upon the infected treated area, rather than the flux of radiated light power/unit area. It is therefore the

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combination of flux in watts/unit area times the exposure time that defines the treatment energy dose.

Claim 45 also includes an optical system as well as an electronic means as previously set forth in original claim 1. There is therefore full support in the application for new claim 45 and entry thereof is considered proper and is respectfully requested.

New claim 47 covers a preferred embodiment of the invention wherein excess heat is removed from the treatment area as disclosed on page 10, lines 23 – 25.

New claims 48 and 49 provide more specific dose ranges of at least 18 Joules/cm^2 and at least 36 Joules/cm^2, respectively. These claims find support in the same descriptive material discussed above in connection with claim 45 and cover the minimum power density (10mW/cm^2) for treatment periods of 30 and 60 minutes, respectively as specifically described in the specification.

New claim 50 covers the employment of a UV filter to remove UV radiation from a light source that may emit the same as described at page 11, lines 3-22. Claim 51 essentially corresponds to the subject matter of original claim 6. Claim 52 covers the embodiment wherein the principal spectral emittance for treating the skin disorder is in the blue/violet range. New claims 53 and 54 correspond to original claims 2 and 3. New claims 55 and 56 provide for spacing the apparatus apart from the treatment area as shown for example in Figure 1.

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New claims 57 and 58 cover delivering the spectral emittance to multiple locations including the sides of the face and chin (the principal site of most acne cases) as shown and described in connection with Figures 9A and 10A (see pages 16, lines 1-17 and page 16, line 30 to page 17, line 17.

New claims 59 and 60 provide for power densities of at least 20mW/cm^2 and 40mW/cm^2 as described in the specification at page 6, lines 16 - 19; page 4, lines 3 - 5; and page 19, lines 15 - 16. The minimum treatment times covered by claims 61-63 are supported in the specification as previously described.

New claim 64 states that the effective treatment area is at least 200cm^2 as described in previous claim 44. New claims 65 - 81 essentially correspond to the subject matter previously covered by original claims 15 - 20 and 37 - 44 noting that laser diodes are included in claims 78 and 79 such as disclosed at page 5, lines 9 – 13. New claim 81 specifically covers acne and seborrhea as the skin disorders as described for example on page 3, lines 9 - 10.

Method claims 82 – 106 essentially mirror the apparatus claims. It should be noted that claims 83 and 84 are particularly directed to the treatment of skin disorders and accompanying inflammation caused by bacteria which produce porphoryins. The method facilitates the production of self-killing peroxides as disclosed on page 1, lines 18 – 23.

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Applicants have determined through in-vitro experiments and clinical studies that the type of spectral emittance, the dose level of the spectral emittance and the application of the same in a plurality, typically several, of discontinuous treatments enables a photodynamic effect that has proven successful in clinical studies (see attached clinical report) in the treatment of skin disorders caused by bacteria such as acne and seborrhea.

The intensity of the treatments and duration of the treatments as well as the discontinuity of the treatments (i.e. the period of time between treatments) provide the opportunity for porphoryins, naturally produced by bacteria, to react with oxygen to produce peroxides and then for the peroxides to kill the bacteria to the extent that at least the bacterial mass is reduced beyond the ability of the bacteria to proliferate.

It is therefore submitted that the newly filed claims are fully supported in the application as filed and entry thereof is deemed proper and is respectfully requested.

The present apparatus is directed to the treatment of skin disorders such as severe acne and seborrhea. As indicated in the specification, the bacteria which causes acne is propionibacterium acnes (P. acne). The formation of acne is evidenced by inflammation of the skin and eventually the formation of pustular regions and cysts. The P. acne bacteria which causes acne has a unique characteristic behavior; it produces porphoryins during its natural metabolism. The prophoyrins accumulate on the external surface of the P. acne cell boundaries. One

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of the objects of the present apparatus is to instigate a photodynamic-photochemical effect in which the porphoryins produced by the bacteria react with oxygen in the presence of selected light spectral bands, to form peroxides. The peroxides are short-lived compounds which are toxic to the bacteria. In particular, peroxides kill the bacteria within several milliseconds of exposure. The present apparatus generates a sufficiently high dose of concentrated radiation especially in the blue/violet range so as to induce the porphoryins to react with oxygen to create a toxic substance which facilitates a form of bacteria the to initiate a form of self destruction. The treatments are spaced apart to enable full development of the self destruct reaction including the time necessary for the porphoryins to reaction with oxygen to form peroxides before reapplication of the dose of light energy.

The apparatus of the present invention generates the required spectral emittance as determined by Applicants and provides a sufficiently high dose level of energy from the desired radiated light so that the bacteria population causing the skin disorder in the treatment area can be eliminated. Since the bacteria are killed indirectly [(i.e. by the conversion of porphoryins to toxic peroxides in the presence of light in selected spectral bands (i.e. blue/violet range of the spectrum)], the apparatus of the present invention must be capable of generating sufficient dose levels (Joules/cm^2) of light energy in the proper spectral bands to initiate the reaction. Furthermore, the apparatus must deliver the dose levels of radiation over

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periods of discontinuous treatment so that there is ample time to react the porphoryins with oxygen to form sufficient quantities of peroxides to kill more of the bacteria than can be expected by the natural proliferation of the bacteria within the treatment area (i.e. reducing the bacterial population).

The present invention employs an apparatus and method in which the application of a narrow spectral band of visible light preferably but not necessarily only in the range of 405-440nm as the principal form of energy, is applied at a dose and for a time sufficient to positively treat the skin disorder by causing a natural product produced by the bacteria (prophoryins) to react in the presence of the treatment induced light with oxygen and thereby in essence destroy itself by contact with the resulting peroxides. Nothing in the prior art teaches or suggests the invention as now claimed in the present application.

Referring to the Office Action, claim 1 stands provisionally rejected under 35 U.S.C. Section 101 as claiming the same invention as claim 4 of Serial No. 10/007,702. This rejection is deemed overcome in light of new claim 45 which requires a dose of at least 9 Joules/cm^2. While Applicants recognize that this is only a provisional double patenting rejection, the foregoing comments are submitted because it is deemed that the rejection should now be withdrawn.

All of the claims of the present application stand provisionally rejected for obviousness type double patenting as being unpatentable over claims 1-22 of co-pending Application No. 10/007/702. Again, Applicants recognize that this is a

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provisional rejection and will address this rejection when the pending application issues as a U.S. Patent.

Page 4 of the Office Action indicates that former claim 15 is indefinite for failure to include proper Markush language. This rejection is deemed overcome in light of the new claims submitted for examination herewith in which proper Markush language has now been employed.

Claims 1, 2, 5-7 and 40-43 stand rejected as anticipated by Diamantopoulos et al. (U.S. Patent No. 4,930,504). The Office Action states that the reference discloses a device for biostimulation of tissue using multiple light sources preferably in the visible red and infrared ranges (column 3, lines 9-10) with possible emission in the whole visible range of 400-700nm. The light source can be a LED or other laser diode. The reference is stated to teach power densities of from 10mW/cm^2 up to 120mW/cm^2. The rejection is hereby traversed and reconsideration is respectfully requested.

Diamantopoulos et al. is directed to a device for biostimulation of tissue employing an array of substantially monochromatic radiation sources (which is a spectral response definition suitable only for LEDs) of a plurality of wavelengths, preferably of at least three different wavelengths. As indicated at column 3, lines 18-22 the three broad ranges of wavelengths include wavelengths in the ultraviolet

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spectra (200-400nm). Thus, the reference does not teach any treatment in which UV radiation is at least substantially absent. For this reason alone, Diamontaopoulos et al. is not an anticipation of the present invention which requires at least the substantial absence of UV radiation.

The reference specifically requires the use of multiple mixed wavelengths and especially multiple wavelengths in the red and infrared spectrum range such as 880nm and 920nm. The reference states that the wavelength mixing effect creates an effective new wavelength in order to provide the required biostimulation effect. This concept of wavelength mixing is explained in the theory of operation at column 7, line 36 to column 9, line 61. The effect of a visible wavelength biostimulation treatment is to provide in-tissue "mixing" of at least two light wavelengths in the infrared spectrum and not direct illumination with a light source in at least the violet/blue spectral band as required in the present invention. Accordingly, claims of the present application, which directly employ a principal light source spectral emission in the 405-440nm wavelength region are not anticipated nor rendered obvious by the Diamontopoulos et al. reference which requires multiple wavelengths mixed together to form a different wavelength of light energy.

As indicated at page 9, beginning at line 18, the object of the reference is to deliver significant amounts of low-power radiation to deeper tissues for short time periods and is therefore directed to treatments of disorders implementing biostimulation effects and not to skin disorders which may be at or near the surface of the skin. The biostimulation treatment of red and preferably infrared spectrum

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radiation is required in the reference. This type of radiation is required in order to insure deeper light energy penetration into the treated tissue, as the radiation with higher wavelength spectrum ensures deeper skin penetration and therefore improved treatment efficiency for the required biostimulation effect and is not directed to the treatment of skin disorders lying at or near the surface of the skin. This reference biostimulation light induced treatment is therefore clearly different than the treatment of acne or related skin disorders by the use of the present invention apparatus and method. The present invention employs generally shorter, non UV, direct wavelength energy for the photodynamic destruction of P. acne bacteria (which resides at or near the surface of the skin) for longer treatment times which are discontinuous as required to initiate the porphoryin-oxygen reaction to generate toxic quantities of peroxides.

Diamontopoulos et al. discloses a treatment energy density of 7.2 Joules/cm^2 as described at page 9, lines 45-47 which is below that required in the present claims. This dose is based on a minimum power density of 120mW/cm^2, which requires placement of the apparatus at the surface of the patient's skin. This is not a preferred procedure for the treatment of acne (see claims 54 and 55) since the present apparatus is typically spaced apart from the patient's skin to provide the capability of treating large areas of the patient's skin while retaining the ability to easily move the apparatus from one location to another. Furthermore, a minimum power density of 120mw/cm^2 to achieve a dose of 7.2 Joules/cm^2 would require a treatment time of only 60 seconds, which is ineffective for achieving adequate

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prophyrin stimulation and a consequential reduction in the bacteria population below the required critical mass needed to effectively treat acne and other skin disorders.

Furthermore, of all of the examples set forth in Diamontopoulos et al., none show the use of a device, which employs a spectral emission within the required wavelength range of 405 - 440nm. Furthermore, all the embodiments disclosed in Diamontopoulos et al. starting from column 10, line 20, up to column 12, line 2, all relate only to LED based light sources in the spectral range of minimum 660nm (red) up to 1500nm (Infra-red). Furthermore, it should be noted that as of the filing date of the reference application (November 13, 1987) LED, emitting light in the spectral range of 405 – 440nm, was not in existence. The first development of violet/blue LEDs began in Japan in 1987 and the first such feasibility prototypes were demonstrated in 1991. Commercial prototypes were available beginning in 1995, which is eight years after the reference application was filed. Thus, the reference does not teach or suggest the feasibililty of constructing a blue emission apparatus and therefore does not cover an apparatus with a monochromatic or a multiple narrow band light source emitting light principally but not exclusively in the spectral band of 405 – 440nm.

Accordingly, the reference does not teach or suggest to one of ordinary skill in the art the treatment of skin disorders which require a minimum dose of at least 9 Joules/cm^2, preferably at least 18 Joules/cm^2 and more preferably at least 36 Joules/cm^2 and require the presence of a principal spectral emission in the range of 405-440nm. To the contrary, Diamontopoulos et al is directed to a multiple

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wavelengths mixing system-employing wavelengths in the red and infrared ranges, well above the range of 405-440nm. For all of these reasons, the claims of the application are not anticipated by nor rendered obvious over Diamontopoulos et al.

Former claims 1, 15, 16 and 18 stand rejected as anticipated by Whitehurst. The Office Action states that the reference discloses light sources including xenon, short arc or metal halide lamps incorporating a cylindrical reflector, which may be used for the delivery of the light to an area. Whitehurst is further stated to disclose a wavelength in the range of 350 to 750nm with a power density of $9W/cm^2$. The rejection is hereby traversed and reconsideration is respectfully requested.

Whitehurst discloses an incoherent or non-laser light source comprising a high-density lamp and a focusing means to provide an output intensity of greater than $0.075W/cm^2$ and a narrow bandwidth spectral output of not more than 30nm. The focus of the reference appears to be on the treatment of cancer cells or for the treatment of portwine stains and the removal of tattoos for very limited exposure times to be controlled by an internal shutter (page 10, line 2) with a typical demonstrated maximum exposure of 2.5 Joule/20mw = 125 sec~ 2 minutes, as indicated in Figure 3a of the reference.

There is no teaching or suggestion in the reference of a photodynamic treatment system for the treatment of acne and other related skin disorders for longer time duration (typically 15 – 30 minutes) and in which there is an initiation by the apparatus spectral band radiation of the reaction of porphoryins and oxygen to

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form toxic peroxides capable of killing enough bacteria so as to arrest the condition. While there is described a method of delivering non-laser light of sufficient intensity to kill cancer cells at a power density of 10 to 200mW/cm^2 (column 3, lines 22-26) there is no teaching or suggestion of providing an apparatus and method by which a particular dose level is administered to carry out the objects of the invention, specifically of at least 9 Joules/cm^2. Indeed, the reference as shown in the drawing Figures uses a maximum dose of only about 2.5 Joules/cm^2. Furthermore, as indicated at column 6, lines 23-30 the reference indicates that UV light may be used for dermatological work. There is no teaching or suggestion of providing a light source with the particular dosage levels required in the present claims in at least the substantial absence of UV radiation.

Former claim 3 stands rejected as obvious over the combination of Diamontopoulos et al. and Tyrell. Tyrell is stated to teach a device using multiple light sources, one of which emits in the blue region. However, the reference is concerned with producing light enhanced sound and has nothing whatever to do with the treatment of acne or the treatment of any skin disorder whatsoever. One of ordinary skill in the art would not look to Tyrell to modify a reference dealing with the treatment of human disorders other than for the well known fact that violet/blue light emits at a wavelength of 420nm.

In view of the foregoing, Applicants submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

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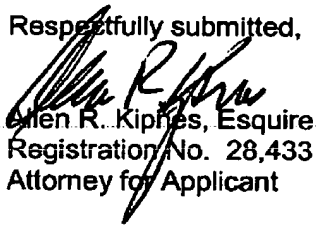
It is believed that no fee is due is connection with this case. However, if any fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,



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